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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,049	12/30/2003	Hans Petersen	05432/100M029-US2	9144
7278	7590	09/24/2004	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			AULAKH, CHARANJIT	
		ART UNIT	PAPER NUMBER	
		1625		

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/750,049	PETERSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 21-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21-41 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. 10/245,824.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. According to a preliminary amendment filed on June 10, 2004, the applicants have canceled claims 1-20 and furthermore, have added new claims 21-41.
2. Claims 21-41 are now pending in the application.

#### ***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 34, 38 and 40 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Petersen ( WO 00/11926, cited on applicant's form 1449 ).  
Petersen discloses a method for the preparation of citalopram. The crystalline free base form (see page 4, lines 1-14 ), pharmaceutical preparation including tablet containing it ( see page 6, lines 1-2 ) and a method of treating depression ( see page 1, lines 9-10 ) using this pure crystalline form of citalopram clearly anticipates the instant claims.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 34, 38 and 40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Boegesoe ( U.S. Patent no. 4,943,590, cited on applicants form 1449 ).  
Boegesoe discloses a process for preparation of citalopram as a crystalline base ( see example 3, lines 12-14 ). The crystalline free base form (see col. 7, line 13 as well as claim 1 ), pharmaceutical preparation including tablet containing it ( see page 8, lines 50-51 and claim 3 ) and a method of treating depression ( see claim 7 ) using this pure crystalline form of citalopram clearly anticipates the instant claims.

Art Unit: 1625

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 21-33, 35-37, 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen ( WO 00/11926, cited on applicant's form 1449 ).

Petersen discloses a method for the preparation of citalopram. The crystalline free base form (see page 4, lines 1-14 ), pharmaceutical preparation including tablet containing it ( see page 6, lines 1-2 ) and a method of treating depression ( see page 1, lines 9-10 ) using this pure crystalline form of citalopram is identical to the subject matter of instant claims except that it does not mention the purity of citalopram free base. However, the pure crystalline citalopram free base is prepared by reacting a cyanide source with the instant impure compound of claim 1 and furthermore, teaches the

Art Unit: 1625

advantage of this process over the prior art processes since it gives improved crystalline and pure product in high yield ( see page 4, lines 9-14 ). However, it would have been obvious and within the ordinary skill of an artesian in the art to calculate the purity of crystalline free base of citalopram since the compound as well as the utility of the compound for treating depression is identical.

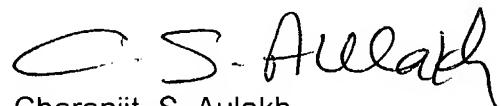
8. Claims 21-33, 35-37, 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boegesoe ( U.S. Patent no. 4,943,590, cited on applicants form 1449 ).

Boegesoe discloses a process for preparation of citalopram as a crystalline base ( see example 3, lines 12-14 ). The crystalline free base form (see col. 7, line 13 as well as claim 1 ), pharmaceutical preparation including tablet containing it ( see page 8, lines 50-51 and claim 3 ) and a method of treating depression ( see claim 7 ) using this pure crystalline form of citalopram is identical to the subject matter of instant claims except that it does not mention the purity of citlopram free base. However, it would have been obvious and within the ordinary skill of an artesian in the art to calculate the purity of crystalline free base of citalopram since the compound as well as the utility of the compound for treating depression is identical.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625